1033 Left Main PTCA: Closure Devices

Monday, March 30, 1998, Noon-2:00 p.m.
Georgia World Congress Center, West Exhibit Hall Level
Presentation Hour: Noon-1:00 p.m.

1033-101 Initial and Long-term Results of Elective Angioplasty in Unprotected Left Main Coronary Artery

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Unprotected left main coronary artery (ULMCA) angioplasty has been considered to be contraindicated. Recent studies suggest that new devices improved its results with relatively small number of patients and short-term follow-up. We analyzed our data of ULMCA angioplasty and evaluated its feasibility and effectiveness.

Methods: Between 2/86 to 8/97, consecutive 145 procedures in 94 patients with ULMCA stenosis were performed electively. There were 82% male and 40% restenosis cases. Final treatments were directional atherectomy (DCA) (50%), balloon angioplasty (41%), and stents (8%). There were 29% three vessel diseases, 19% heart failure and/or unstable angina, 32% age ≥75, 65% prior MI, 6% prior CABG, and 22% EF < 35% cases. Follow-up angiography was scheduled at 1 day and at 3, 6, and 12 months after angioplasty.

Results: 1) Initial results: ULMCA stenoses of 140 cases (97%) were improved to ≤50%. There were 2 (1.4%) cardiac death, 3 (2.1%) non-cardiac death, 2 (1.4%) QMI, 7 (4.8%) non-QMI, 10 (6.9%) repeat angioplasty, and 0 (0%) CABG. 2) Restenosis rate: Restenosis rate was 35.2% within 3 months, and 47.0% within 1 year. The restenosis rate of DCA was 26.3% and lower than that of balloon angioplasty (63.2%, $p < 0.0005$) and that of stents (44.4%, p = NS). 3) Long-term results of 94pts: Mean follow-up period was 2.8 years. Three-year survival rate was 80.6%, and 3-year cardiac survival rate was 90.0%.

Conclusions: ULMCA angioplasty is feasible and effective under scheduled angiographic follow-up. DCA is promising procedure for ULMCA stenosis because of its lower restenosis rate.

1033-102 Directional Atherectomy or Stenting for Unprotected Left Main Coronary Stenoses – The ULTIMA Group Experience

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Encouraging results from modest series of patients (pts) have been reported for both directional atherectomy (DCA) and stents (S) used to treat pts with unprotected left main stenoses (ULMS). To compare their relative benefit we queried a registry of 229 non acute MI consecutively treated ULMS pts from 25 centers treated since 1/94. Follow-up angio was 75% complete at 6 ± 3 mos.

	DCA (n = 46)	Stent (n = 148)
Age (yrs)	68 ± 10	64 ± 14
LVEF (%)	54 ± 14	54 ± 15
Rest or progressive angina (%)	30.4	40.1
Moderate-severe calcium (%)	21.7	28.0
Distal ULMS (%)	69.6	47.7
Bypass status-high risk (%)	21.7	28.6
Inoperable (%)	2.2	15.0
In hospital death, MI, CABG (%)	4.3	5.5
Restenosis (%)	21.7	27.5
6 month death, MI, revasc (%)	23.0	32.6

After adjusting for these and other variables in Cox analysis, there was no difference between DCA and stents for 6 month outcome (p = 0.26). Both appear promising for treatment of ULMS, but need to be formally compared with CABG.

1033-103 Mechanical Approach in the Recanalization of Total Coronary Occlusions: A Consecutive Series of 322 Lesions

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From January 1996 to July 1997 interventions on 322 consecutive total coronary occlusions (301 patients) were attempted at our institution according to a standardised protocol. This protocol consisted in the use of first a floppy, hydrophilic coated wire (Choice PT-Scimed) followed in case of no success by a 0.014 or 0.010 inch standard wire (Athlete-Asahi; In-torque-ACS). Furthermore in all cases low profile over-the-wire balloons (Ranger-Scimed; Predator-Cordis) were used to support the wire.

The age of occlusion was ≤4 weeks in 5%, >4 weeks and ≤3 months in 28%, >3 months in 35% and undetermined in 32% of cases. Bilateral injections in case of presence of retrograde contralateral filling were used in 38% of cases. The overall mechanical crossing success was 73%. The floppy wire successfully crossed the occlusion in 44% of cases, a stiff wire in 21% and the combined use of a floppy and a stiff wire, both determinant for the progression in the occlusion in 8%. After mechanical crossing failure a laser wire was used in 7 occlusions (2%) with a 43% success rate. Procedural success with re-established TIMI 3 anterograde flow was achieved in 62% of all lesions. Stents were used in 72%, rotational atherectomy in 12% and directional atherectomy in 10% and laser atherectomy in 4% of cases. Complications were: 1 death (0.3%), 5 urgent CABG (2%), 3 perforations with tamponade (1%), 2 Q wave infarction (0.6%), 5 non Q wave infarction (2%) and 25 cases of local contrast staining (8%). Two-hundred-ten lesions were treated 6 months before present time and therefore eligible for angiographic follow up which was obtained in 60%. The ≥50% diameter restenosis rate was 40%.

Conclusions: The "old" mechanical recanalization technique using "new" wires and balloons has a high success and low complication rate. Results of emerging new recanalization devices need to be compared with present data.

1033-104 Immediate Post PTCA Percutaneous Suture of Femoral Arteries With the Perclose Device: Results of High Volume Users

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Background: The reported results of percutaneous arterial sutures using Perclose devices (Techstar/Prostar) are contradictory and most reported series include the learning curve of the users.

Methods: To overcome these drawbacks, a prospective single center study was carried out with 2 physicians whose individual experience was >250 arterial sutures immediately after PTCA.

Results: 104 consecutive pts (77.8% male, mean age 60.9 yrs) were treated. The device used was 6F 2 needles (80 pts), 8F 2 needles (20 pts) and 8F 4 needles (4 pts). Mean ACT at the time of closure was 426.3 s (188 to 1500 s). Mean procedural time was 3.19 mn (1.23 to 10.30 min). The suture was immediately effective in 93 pts (89.4%) who did not require compressive bandage, leg immobilization or bed confinement (Group 1). In the remaining cases bleeding was treated with Femostop, applied <1 hr. in 8 cases (Group 2). The pts were then managed as Group 1 (no compression, no immobilization). Femostop was applied for 1 to 3 hrs. in 3 cases followed by compressive bandage and 12-hr leg immobilization (Group 3). At discharge, no cases of hematoma were observed in Group 1 and 2 (97%). In Group 3, 1 pt had surgery for a false aneurysm and 1 pt had an uncomplicated small hematoma. All pts were followed by phone at day 15. No late complications occurred.

Conclusion: After a prolonged learning curve period, closure of femoral arteries with Perclose device is fast, effective and improves dramatically patient comfort in the post procedural period. The potential decrease in access site complication rate together with shorter hospital stay may balance the cost of the device.

1033-105 A Small Plug for a big Hole: Safety and Efficacy of Eight French Angioseal™ for Closure of Nine French Arteriotomy Site Immediately Following Percutaneous Coronary Interventions

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In selected percutaneous coronary intervention procedures, 9 French (Fr) guide catheters are used for stronger support, larger lumen and better visu-

	9 Fr (N = 32)	8 Fr (N = 55)	P value
Age (year)	63 ± 12	67 ± 13	NS
ACT* (sec)	261 ± 84	261 ± 80	NS
TTH† (sec)	233 ± 742	338 ± 1060	NS
Male	60%	72%	NS
Hematoma >6 cm	0%	2%	NS
Transfusion	0%	0%	NS
Vascular Repair	0%	0%	NS

(* = activated clotting time at sheath removal, † = Time to Hemostasis)

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alization compared with smaller size catheters. We seek to determine if the recently approved 8 Fr Angioseal™ device, with its unique 2 × 10 × 1 mm polymer anchor and 26 mg collagen plug construct, can be use for closure of 9 Fr arteriotomy site immediately following percutaneous interventions. We compared pt characteristics and incidence of major in-hospital vascular complications following Angioseal™ placement in 87 consecutive pts following either 8 or 9 Fr intervention procedures (table).

We Conclude: The use of 8 Fr Angioseal™ is safe and effective for access site closure immediately following percutaneous intervention utilizing either 8 or 9 Fr sheath system.

1033-106 Effects of a New Vascular Sealing Device on Coagulation Parameters and Thrombin Generation in Humans

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Background: We evaluated a new vascular sealing device (DUET) which incorporates a unique low-profile disk-shaped balloon delivery catheter and a procoagulant (thrombin/collagen suspension) delivered to the adventitial surface of the arterial puncture site immediately following percutaneous vascular interventions.

Methods: Following a diagnostic or PTCA procedure, 24 pts. underwent immediate placement of the DUET sealing device in the cath lab. In all pts., coagulation markers and tests for intravascular thrombin generation were performed pre and post DUET deployment, and at the 30 day followup evaluation.

Results:

	Fibrinogen	D-dimer	F1.2
Pre-DUET	332 (133–542)	180 (40–760)	1.2 (0.60–3.21)
Post-DUET	33.3 (194–308)	515 (180–2620)	1.8 (0.82–8.14)
30 day F/U	291 (213–892)	320 (40–8700)	1.3 (0.68–4.19)

No major in-hospital complications occurred. There was no clinical evidence of intravascular thrombosis in any pt. treated.

Conclusions: Despite the use of a powerful procoagulant suspension delivered to the adventitial surface of the arterial puncture site, the DUET vascular sealing device was not associated with any evidence of excessive intravascular coagulation or thrombin generation. These results paralleled the pts. favorable clinical course.

1034 Approaches to Inhibiting the Postinterventional Proliferative Response

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1034-98 Cyclic Thermal Treatment of Coronary Arteries Limits Smooth Muscle Cell Proliferation Following Balloon Injury: Results in a Porcine Coronary Organ Culture System

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Low temperature heat treatment induces heat shock proteins (HSP), which have been shown to be cytoprotective. The effect of heat shock protein induction on the smooth muscle cell (SMC) response to injury is unknown. We hypothesized that the arterial response to injury may be modified by periodic, low-level heat exposure. This study examined the effect of cyclic thermal treatment on the induction of HSP, SMC proliferation, apoptosis and iNOS expression using a porcine organ culture system.

Methods: In 8 normal pigs, 16 coronary arteries were dilated with 3.5 mm angioplasty balloon for 60 seconds at 8 atm. Immediately after angioplasty the arteries were dissected free, cut into 5 mm rings, and placed in culture media supplemented with 20% fetal calf serum. The injured coronary rings were divided into 2 groups: cyclic heat treated and controls. In the cyclic heat-treated group, coronary rings were placed in 43°C media for 20 minutes daily for 10 days after injury, and then returned to 37°C.

Results: In the heat-treated group, intimal area was reduced by 30% (1.02 ± 0.11 vs. 1.45 ± 0.21 mm^2; $p < 0.05$) compared to the untreated group. The number of α actin and PCNA labeled cells was significantly decreased (35% and 33%, respectively). Heat treated intima contained significantly more HSP staining than did untreated (145 ± 22 vs 33 ± 6 cells/mm^2; $p < 0.05$). Expression of apotosis (TUNEL labeling) and immunohistochemical expression of iNOS were increased by 43% (103 ± 25 vs. 72 ± 15 cells/mm^2; 1; $p < 0.05$) and 37% (96 ± 15 vs. 70 ± 9 cells/mm^2; $p < 0.05$) in the 43°C treated group respectively.

Conclusion: Low levels of periodic thermal therapy through induction of heat shock proteins, apoptosis and iNOS expression may limit SMC proliferation after balloon injury.

1034-99 Tumor Necrosis Factor Alpha Blood Levels as a Potential Marker of Stenosis in Patients Undergoing Percutaneous Transluminal Coronary Balloon Angioplasty

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Background: There is growing evidence that immune-inflammatory reactions are involved in restenosis phenomena; cytokine signal plays a role in the modulation of cellular functions and proliferation of intimal smooth muscle cells. The aim of this study was to investigate if tumor necrosis factor alpha (TNF_α) serum concentration may identify subjects at high risk of restenosis after percutaneous transluminal coronary balloon angioplasty (PTCA).

Methods: We have estimated TNF_α blood concentrations (available ELISA kit, normal values 0.8–2 pg/ml) in 35 patients (26 males, mean age 61.5 ± 5.5 yr.) with documented unstable angina and single coronary vessel disease before undergoing PTCA. Patients underwent clinical evaluation, coronary angiography and a supine bicycle echo-stress, three months after the PTCA procedure.

Results: Normal TNF_α values (1.54 ± 0.34 pg/ml) were found in 25 patients; at follow up, 23/25 had neither clinical signs of ischema, nor angiographically documented restenosis, nor an ischemia-positive echo-stress, 2/25 presented restenosis. 10/35 had abnormally high TNF_α blood values (12.65 ± 2. 3 pg/ml), 9 of these ten patients showed restenosis at coronary angiograms and 8 of them positive Eco-stress. Positive predictive value for restenosis was 90%, negative predictive value was 92%.

Conclusions: These results show that high serum TNF_α levels are associated to an high risk of restenosis; this marker of restenosis is easily estimated at low post and could be very helpful in revascularization timing and in the decision making for interventional procedures.

1034-100 Parameters Influencing Local Gene Delivery Following Angioplasty in Rabbit Single and Double Injury Models

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Background: We recently demonstrated a high frequency of vascular smooth muscle cells (VSMC) apoptosis immediately following angioplasty of normal vessels. Here we analyzed the effect of balloon:artery ratio (BAR) on the frequency of VSMC apoptosis and the efficiency of local gene delivery in single and double injury models of restenosis in rabbit iliac arteries.

Methods and Results: New-Zealand White rabbits (n = 36) underwent iliac angioplasty with either a 2.5 mm (BAR 1.08 to 1.13) or a 3.0 mm balloon (BAR 1.29 to 1.34). Arteries were harvested at different timepoints (30 min, 4 hours and 3 days) to determine cellularity and apoptosis (TUNEL staining). In the single injury model, the 3.0 mm balloon induced a 60.6% reduction in cellularity ($p < 0.001$) while the 2.5 mm balloon did not show a significant effect. The hypocellularity of the media at day 3 was correlated with a higher level of TUNEL+ cells at 30 minutes when compared to the 2.5 mm balloon. In the double injury model, the effect of the 3.0 mm balloon was even more pronounced, with a 91.1% reduction in the cellularity of the media ($p < 0.001$). Cellularity was also reduced in the neointima (36.6% reduction, $p = 0.025$). At 30 min, TUNEL+ cells were abundant in both the media and the neointima of 3.0 mm balloon-injured arteries when compared to 2.5 mm balloon-injured arteries. Parallel studies demonstrated that the transfection efficiency of a reporter gene (adeno-βGal) to the vessel wall using a channel balloon was significantly reduced when a higher BAR was used.

Conclusions: 1) Angioplasty induces early hypocellularity that is proportional to the severity of the balloon injury. 2) This hypocellularity is due, at least in part, to rapid onset apoptosis and is associated with a lower efficiency in local gene delivery to the vessel wall.